



NEWS RELEASE

Marty J. Jackley

South Dakota Attorney General

Charles McGuigan

Chief Deputy Attorney General

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CONTACT: Sara Rabern (605)773-3215

Attorney General Jackley and 41 Other State Attorneys General Reach a \$35 Million Consumer Settlement with Pfizer

PIERRE, S.D – Attorney General Marty Jackley has joined 41 other Attorneys General in reaching a \$35 million settlement with Pfizer Inc, who as parent of Wyeth Pharmaceuticals Inc. agrees to be bound by the judgment, to resolve allegations that Wyeth unlawfully promoted Rapamune, an immunosuppressive drug currently approved by the FDA as prophylactic for organ rejection after kidney transplant surgery. It is alleged that Wyeth violated state consumer protection laws by misrepresenting the uses and benefits of Rapamune, including making representations related to the unapproved use of Rapamune following an organ transplant other than a kidney transplant, the unapproved protocol of converting patients to Rapamune after initially receiving a different immunosuppressive drug and using Rapamune in unapproved drug combinations. South Dakota's share of this settlement is \$419,000.

"These misleading claims put consumers' health at risk. This settlement and court judgment serves to hold the pharmaceutical company accountable and protects the public in the future," said Jackley.

The Consent Judgment requires Pfizer to ensure that its marketing and promotional practices do not unlawfully promote Rapamune or any Pfizer product including:

- Make, or cause to be made, any written or oral claim that is false, misleading, or deceptive regarding any Pfizer Product;
- Make any claim comparing the safety or efficacy of a Pfizer Product to another product when that claim is not supported by substantial evidence as defined by Federal law and regulations;
- Promote any Pfizer Product for Off-Label uses;
- Include mechanisms in its financial incentives to provide incentive compensation for sales that may be attributable to the Off-Label uses of any Pfizer Product;
- Affirmatively seek the inclusion of Rapamune in hospital protocols or standing orders unless Rapamune has been approved by the FDA for the indication for which it is to be included in the protocol or standing order;
- Disseminate information describing any Off-Label or unapproved use of Rapamune unless such information and materials comply with applicable FDA regulations and the recommended actions in FDA Guidances for Industry; or
- Seek to influence the prescribing of Rapamune in hospitals or transplant centers in any manner (including through funding clinical trials) that does not comply with the Federal anti-kickback statute.

